REMARKS

I. Background

The present Amendment is in response to the Final Office Action mailed December 1, 2005, and the Advisory Action mailed June 15, 2006. Since claims 1- 43 have been previously cancelled, claims 44-54 were pending in the application for consideration at the time of the mailing of the Final Office Action. Claims 44-46 are currently amended. Claims 44-54 are still pending for consideration.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

II. Proposed Claim Amendments

Please amend the claims in the manner indicated above, where an underline represents new text, and strikeouts are used to indicate deleted text. The amendments to claims 44-46 have been made to place the claims in condition for allowance, and are fully supported by the application as originally filed. Thus, Applicant submits that the amendments to the claims do not introduce new matter and entry thereof is respectfully requested.

III. Rejection on the Merits

A. Rejections Under 35 U.S.C. § 101, Statutory Double Patenting

The Office Action has rejected claims 44-54 under 35 U.S.C. § 101 as claiming the same invention as that of claims 1-5, 31-36, 41, 54, and 58-61 of prior U.S. Patent No. 6,518,021.

Applicant respectfully asserts that the claims, as pending at the time of the rejection, were not coextensive in scope compared to the claims of U.S. Patent No. 6,518,021.

Applicant respectfully asserts that a "subunit of a component" is not coextensive in scope as "a component" as alleged in the Office Action. In part, this is because a subunit, by definition, is less than the whole component. It is well known in the art, as well as described in the application, that you can create a plasmid that only encodes for a portion (*i.e.*, subunit) of a protein (*i.e.*, component). Therefore, you can have "a nucleotide sequence coding for a hybrid polypeptide comprising a luminophore linked to the subunit" without the subunit being included within the whole component.

Contrary to the allegations in the Advisory Action, the application provides many examples of components and subunits of components. For example, the application exemplified a "component" by a "biologically active peptide" and exemplified a "subunit" as a "part thereof" in reference to the "biologically active peptide" (*see* paragraph [0044]). Additionally, the Examples distinguish between a subunit and a compound. For example, the Application states, "In one embodiment the biologically active polypeptide encoded by the nucleic acid construct is a protein, or a part thereof." Further, it is well known in the art that a protein is a component of a pathway and a subunit is part of a protein.

The Advisory Action further alleges that a component, even if treated as a fully functional protein, can still be considered to be a subunit because a fully functional protein involved in the intracellular pathways can bind to other fully functional proteins to form a complex, where the individual protein is a component of the complex. Applicant respectfully disagrees and asserts that the combination of proteins would be a combination of components that form a complex. By plain meaning, a component is a constituent part or element of something, such as a complex, that includes the component. As such, a complex is comprised of components. It is well known in the art that protein complexes are formed of individual protein components, and proteins are comprised of subunits.

In the example provided in the Office Action, NF-kB and IkB are proteins that form a complex, and the NF-kB and IkB are components of the complex. Further none of the examples of components in the application are complexes as asserted by the Office Action (*see* Examples 4-9, 11-20). On the other hand, a subunit would be a portion of either the NF-kB or IkB. The examples of subunits provided in the application are portions of components. Specifically, Example 1 identifies the catalytic subunit of the murine cAMP dependent protein kinase (PKAc)

which is fused with GFP. In no instance is a component of a complex considered a subunit of the complex. By applicant's lexicography, the protein of a complex is a component, and a portion of the protein is a subunit. Thus, a subunit is distinct from a component and is a portion of a component, and a component is distinct from a complex and is a portion of a complex.

Furthermore, Applicant has amended claims 44-46 to include elements not present in the claims of U.S. Patent No. 6,518,021. As such, currently pending claims do not claim the same invention as U.S. Patent No. 6,518,021. Thus, Applicant respectfully requests withdrawal of the statutory type double patenting rejection.

B. Rejections Under 35 U.S.C. § 102

The Office Action has rejected claims 44-52 under 35 U.S.C. § 102(b) as being anticipated by *Carey et al.* (J. Cell Biol., June 1996). Applicant has amended the independent claims, thereby rendering the rejection moot.

Carey teaches a heterologous fusion protein (GR-GFP) comprising a glucoid receptor (GR) coupled to green fluorescent protein (GFP) (page 986). Dexamethasone, which is well known to affect the translocation properties of GR, was used to determine whether or not GR-GFP had the translocation properties of GR (page 986). As such, *Carey* shows that the GR-GFP had translocation properties of GR when exposed to dexamethasone so that the GR-GFP could be used in a system useful for studying nuclear transport in vivo (page 986). However, *Carey* is completely devoid of screening a compound to determine whether the compound is a biologically active compound that affects GR translocation. In part, this is because it is already well known that dexamethasone has an affect on the GR, and it is only used to confirm that the GR-GFP can be used as a model for GR. As such, *Carey* is devoid of teaching a method of screening. Further, *Carey* is completely devoid of screening a library of compounds to determine whether the library includes a compound that is biologically active. Furthermore, *Carey* is completely devoid of screening a library of substances that is comprised of substances having unknown influences on the intracellular translocation of the subunit.

Applicant respectfully asserts that *Carey* does not teach or suggest each and every element of the claimed invention. First, *Carey* does not teach or suggest a "method for screening a library of substances to detect a biologically active substance by detecting intracellular translocation of a subunit of a component." Second, *Carey* does not teach or suggest such screening by "incubating the one or more cells with at least one substance of the library of

substances having unknown influences on the intracellular translocation of the subunit." Third, *Carey* does not teach or suggest "screening the at least one substance of the library of substances for biological function or biological effect in the one or more cells." Thus, *Carey* does not teach or suggest each and every element of the claimed invention.

Since *Carey* does not teach or suggest each and every element of the claimed invention, claims 44-52 are not anticipated. Accordingly, Applicant respectfully requests withdrawal of the rejection to claims 44-52 under 102(b).

C. Rejections Under 35 U.S.C. § 103

The Office Action has rejected claims 53-54 under 35 U.S.C. § 102(b) as being unpatentable over *Carey et al.* (J. Cell Biol., June 1996) as applied to claims 44-52 above, and further in view of *Cormack at al.* (Gene, 1996). Applicant has amended the independent claims, thereby rendering the rejection moot.

According to the applicable law, a claimed invention is unpatentable for obviousness if the differences between it and the prior art "are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." 35 U.S.C. § 103(a) (2005); *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966); MPEP 2142. Obviousness is a legal question based on underlying factual determinations including: (1) the scope and content of the prior art, including what that prior art teaches explicitly and inherently; (2) the level of ordinary skill in the prior art; (3) the differences between the claimed invention and the prior art; and (4) objective evidence of nonobviousness. *Graham*, 383 U.S. at 17-18; *In re Dembiczak*, 175 F.3d 994, 998 (Fed. Cir. 1999). It is the initial burden of the PTO to demonstrate a *prima facie* case of obviousness, which requires the PTO to show that the relied upon references *teach or suggest* all of the limitations of the claims. MPEP 2142 (emphasis added).

According to MPEP section 2143:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable

> expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991)." (emphasis added).

The Office Action cites *Cormack* because it teaches "mutations of GFP, including the F64L and S65T" (Final Office Action, page 6). However, *Cormack* is completely devoid of a teaching regarding screening a compound to determine whether the compound is a biologically active compound. Further, *Cormack* is completely devoid of a teaching regarding screening a library of compounds to determine whether the library includes a compound that is biologically active. Thus, *Cormack* does not cure the deficiencies recited above with respect to *Carey*.

Accordingly, Applicant respectfully asserts the combination of *Carey* and *Cormack* does not teach or suggest each and every element of the claimed invention. Specifically, the combination of *Carey* and *Cormack* does not teach or suggest the elements recited above that are not taught by *Carey* alone.

Since the combination of *Carey* and *Cormack* does not teach or suggest each and every element of the claimed invention, a *prima facie* case of obviousness has not been established. Accordingly, Applicant respectfully request withdrawal of the rejection to claims 52-54 under 103.

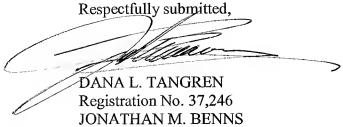
SUMMARY

Applicant believes the amendments to the claims have placed claims 44-54 in allowable form. Thus, Applicant respectfully requests reconsideration.

In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 29 day of August 2006.

Respectfully submitted,



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